



Complete Summary

GUIDELINE TITLE

Primary prevention of cardiovascular disease and type 2 diabetes in patients at metabolic risk: an Endocrine Society clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Rosenzweig JL, Ferrannini E, Grundy SM, Haffner SM, Heine RJ, Horton ES, Kawamori R, Endocrine Society. Primary prevention of cardiovascular disease and type 2 diabetes in patients at metabolic risk: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2008 Oct;93(10):3671-89. [144 references]
[PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Components of metabolic syndrome, including:

- Hypertension
- Lipid abnormalities
 - Elevated apolipoprotein B-containing lipoproteins (low-density lipoprotein [LDL], very-low-density lipoprotein [VLDL])
 - Elevated triglycerides
 - Reduced levels of high-density lipoprotein cholesterol (HDL-C)
- Hyperglycemia

- Prediabetes (impaired fasting glucose [IFG] and impaired glucose tolerance [IGT])
- Abdominal adiposity (enlarged waist circumference)
- Prothrombotic state
- Proinflammatory state

GUIDELINE CATEGORY

Diagnosis
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide clinical practice guidelines for the primary prevention of cardiovascular disease and type 2 diabetes mellitus in patients at metabolic risk

TARGET POPULATION

Patients at high metabolic risk for cardiovascular disease (CVD) or type 2 diabetes mellitus (T2DM), including individuals with:

- Elevations of apolipoprotein B (apo B)-containing lipoproteins (low-density lipoprotein [LDL] and very-low-density lipoprotein [VLDL]) with elevated triglycerides
- Reduced levels of high-density lipoprotein cholesterol (HDL-C)
- Increased plasma glucose levels
- Hypertension
- Enlarged waist circumference
- A prothrombotic state
- A proinflammatory state

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Diagnosis/Risk Assessment

1. Routine clinical evaluations (weight, body mass index (BMI) , waist circumference)
2. Methods of defining risk
3. Screening intervals
4. Identification of diabetes and cardiovascular disease (CVD) risk factors:
 - Family history
 - Low density lipoprotein-cholesterol (LDL-C)
 - Oral glucose tolerance test (OGTT) or fasting plasma glucose (FPG)
 - C-reactive protein (CRP) (and other biological markers that are not recommended)
 - Coagulation and antifibrinolytic factors
5. Ten-year global risk assessment for patients identified with metabolic risk

Treatment/Prevention

Atherosclerotic Cardiovascular Disease

1. Lifestyle management (first-line therapy)
2. Lipoprotein lowering therapy (e.g., statins, fibrates, combination therapy), adjusted to the absolute 10-yr risk
 - Lowering of LDL-C levels (primary target)
 - Raising high-density lipoprotein (HDL-C) levels (secondary target)
3. Lowering of blood pressure (dietary restrictions, antihypertensive drugs)
4. Prophylactic aspirin use

Type 2 Diabetes Mellitus (T2DM)

1. Lifestyle management
 - Weight reduction
 - Physical activity
 - Dietary modification
2. Drug therapy (not recommended)

MAJOR OUTCOMES CONSIDERED

- Incidence of cardiovascular disease (CVD)
- Incidence of type 2 diabetes mellitus (T2DM)
- Morbidity
- Mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of the Evidence

+000 Denotes very low quality evidence

++00 Denotes low quality evidence

+++0 Denotes moderate quality evidence

++++ Denotes high quality evidence

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Task Force elected to use the approach recommended by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) group.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Participants

The Task Force was composed of a chair, selected by the Clinical Guidelines Subcommittee (CGS) of The Endocrine Society, six additional experts, one methodologist, and a medical writer.

Evidence

Systematic reviews of available evidence were used to formulate the key treatment and prevention recommendations. The authors used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) group criteria to describe both the quality of evidence and the strength of

recommendations. The authors used 'recommend' for strong recommendations and 'suggest' for weak recommendations.

Consensus Process

Consensus was guided by systematic reviews of evidence and discussions during one group meeting, several conference calls, and e-mail communications.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

- The number 1 indicates a strong recommendation and is associated with the phrase "The Task Force recommends."
- The number 2 denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The drafts prepared by the task force with the help of a medical writer were reviewed successively by The Endocrine Society's Clinical Guidelines Subcommittee (CGS), Clinical Affairs Committee (CAC), and Council. The version approved by the CGS and CAC was placed on The Endocrine Society's Web site for comments by members. At each stage of review, the Task Force received written comments and incorporated needed changes.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the quality of the evidence (+000, ++00, +++0, and ++++); the strength of the recommendation (1 or 2); and for the difference between a "recommendation" and a "suggestion" are provided at the end of the "Major Recommendations" field.

1. Definitions and Diagnosis

There is growing evidence that many patients who develop cardiovascular disease (CVD) or type 2 diabetes mellitus (T2DM) have common antecedents of metabolic origin. Although the pathophysiology underlying these antecedents is not fully understood, there is a strong overlap between cardiovascular risk factors and

prediabetes (impaired fasting glucose [IFG] and impaired glucose tolerance [IGT]). For this reason, it is reasonable to identify a general condition called metabolic risk.

The Task Force decided to define metabolic risk as reflecting an individual's risk for CVD and T2DM (see the appendix in the original guideline document for a full discussion of this choice of terminology). Individuals at high metabolic risk often have:

1. Elevations of apolipoprotein B (apo B)-containing lipoproteins (low-density lipoprotein [LDL] and very-low-density lipoprotein [VLDL]) with elevated triglycerides
2. Reduced levels of high-density lipoprotein cholesterol (HDL-C)
3. Increased plasma glucose levels
4. Hypertension
5. Enlarged waist circumference
6. A prothrombotic state
7. A proinflammatory state

1.1. The Task Force did not attempt to reach consensus on endorsement of a specific definition of the metabolic syndrome. The two currently used definitions describe closely overlapping but not identical populations (see Table 1 below.) Of the most commonly used definitions of the metabolic syndrome, the Task Force suggests that physicians screen for the components of the American Heart Association/National Heart, Lung, and Blood Institute (AHA/NHLBI) definition at the clinical visit, because of its ease of use and convenience of implementation in the office setting. The finding of at least three components especially should alert the clinician to a patient at metabolic risk (at higher risk for CVD and T2DM] (2 | +000).

Table 1: Criteria Proposed for Clinical Diagnosis of the Metabolic Syndrome

Clinical Measure	AHA/NHLBI: any 3 of the following 5 features	IDF
Waist circumference	≥102 cm in men or ≥88 cm in women (non-Asian origin); ≥90 cm in men or ≥80 cm in (both East Asians and South Asians)	≥94 cm in men or ≥80 cm in women (Europids, Sub-Saharan Africans, and Middle Eastern); ≥90 cm in men or ≥80 cm in women (both East Asians and South Asians; South and Central Americans); ≥85 cm in men or ≥90 cm in women (Japanese), plus any 2 of the following:
Triglycerides (fasting)	≥150 mg/dl or on drug therapy for high triglycerides	≥150 mg/dl or on drug therapy for high triglycerides
HDL-C	<40 mg/dl in men or <50 mg/dl in women or on drug therapy for low HDL-	<40 mg/dl in men or <50 mg/dl in women or on drug therapy for low HDL-C

Clinical Measure	AHA/NHLBI: any 3 of the following 5 features	IDF
	C	
Blood pressure	≥130 mm Hg systolic or ≥85 mm Hg diastolic or on drug therapy for hypertension	≥130 mm Hg systolic or ≥85 mm Hg diastolic or on drug therapy for hypertension
Glucose (fasting)	≥100 mg/dl or drug therapy for elevated glucose	≥100 mg/dl (includes diabetes)

AHA/NHLBI: American Heart Association/National Heart, Lung, and Blood Institute; IDF: International Diabetes Foundation

1.2. The Task Force recommends that providers screen for the main components of the metabolic syndrome at regular intervals (1 | ++ +0). The Task Force suggests that this should be done at least every 3 yr (2 | +000) in those individuals who have one or more risk factors but do not meet the established definitions of the syndrome. These components include measurement of blood pressure, waist circumference, fasting lipid profile, and fasting glucose.

1.3. The Task Force recommends that waist circumference be measured by clinicians as a routine part of the clinical examination. This measurement does not replace the routine measurement of weight or calculation of body mass index (BMI) but can provide more focused information regarding risk for CVD and T2DM (1 | +000).

The Task Force recommends that the cutoffs for elevated waist circumference be at least 102 cm for men and at least 88 cm for women in Caucasian, African-American, Hispanic, and Native American populations. The Task Force recommends that the cutoffs for waist circumference in Asian populations (both East Asian and South Asian) be at least 90 cm for men and at least 80 cm for women (1 | +000).

1.4. The Task Force suggests that individuals previously diagnosed with prediabetes (IGT or IFG) be screened for the presence of overt T2DM at 1- to 2-year intervals (2 | +000). This can be done with fasting plasma glucose (FPG) and, wherever possible, with an oral glucose tolerance test (OGTT). For individuals at metabolic risk without IFG, there is less consensus on the recommended interval of screening.

1.5. A number of additional biological markers have been associated with metabolic risk: apo B, adiponectin, leptin, fasting insulin or proinsulin, free fatty acids, homocysteine, plasminogen activator inhibitor-1 (PAI-1), fibrinogen, alanine transferase (ALT) as a marker of liver fat, C-reactive protein (CRP), inflammatory cytokines (e.g., IL-6), liver or myocellular fat content by magnetic resonance (MR) spectroscopy, and microalbuminuria (in patients without diabetes). Evidence that these markers provide an indication of metabolic risk beyond routine

measurements is limited. Their measurement is not recommended for routine evaluation of metabolic risk in clinical practice. (2 | +000).

Some of the above measurements may have utility for determining the pattern or severity of metabolic risk, but must be considered as optional based on clinical judgment. Although these measures are not recommended for routine measurement, one or more of them may be measured according to physician discretion to confirm or clarify estimates of metabolic risk.

2. Absolute Risk Assessment

2.1. The Task Force recommends that all patients identified as having metabolic risk undergo global risk assessment for 10-year risk for either coronary heart disease (CHD) or CVD. Framingham and Prospective Cardiovascular Munster (PROCAM) scoring assesses 10-year risk for CHD. The European systematic coronary risk evaluation (SCORE) algorithm predicts 10-year risk for total cardiovascular mortality. Risk factor scoring with these algorithms can be easily carried out. Global risk assessment for cardiovascular outcomes is recommended before starting preventative treatment (1 | +000).

3. Treatment to Prevent Atherosclerotic CVD (Especially CHD and Stroke)

3.1.1. The Task Force recommends that apo B-containing lipoproteins (LDL and VLDL) be lowered in patients at metabolic risk to reduce risk for CVD (1 | +++++).

3.1.2. The Task Force recommends that LDL cholesterol (LDL-C) be the primary target of lipoprotein-lowering therapy (1 | +++++) and that non-HDL-C (an indicator for all apo B-containing lipoproteins) be the secondary target (1 | ++++0). Furthermore, if HDL-C remains reduced after treatment of non-HDL-C, consideration can be given to therapies designed to raise HDL-C (2 | ++00).

3.1.3. The Task Force recommends that intensity of lipoprotein lowering therapy be adjusted to the absolute 10-year risk for CVD. (1 | ++00) The Task Force suggests that intensity of lipoprotein-lowering therapy further be adjusted to the absolute lifetime risk for CVD (2 | +000).

3.2.1. The Task Force recommends that when blood pressure is elevated, it be lowered to reduce the risk for CVD (1 | +++++).

3.2.2. The Task Force recommends that type and intensities of blood pressure-lowering therapies be selected to optimize risk reduction, safety, and cost-effectiveness. The Task Force recommends that blood pressure be treated to a target of less than 140/90 mm Hg (or <130/80 in individuals with diabetes or chronic kidney disease). If weight loss or lifestyle modifications are not successful, then antihypertensive medications should be instituted and dose adjusted to treat to target (1 | ++++0).

3.3 The Task Force recommends that lifestyle management be considered first-line therapy for patients at increased metabolic risk (1 | +000).

3.4.1. The Task Force recommends that the prothrombotic state be treated with lifestyle therapies to reduce risk for CVD (1 | +000).

3.4.2. In individuals at metabolic risk who are over age 40 and whose 10-yr risk is more than 10%, the Task Force recommends that lowdose aspirin prophylaxis for primary prevention of CVD (75–162 mg/d) be considered if there are no contraindications (1 | +++0).

There is no consensus on the specific recommended dose within this range.

4. **Treatment to Prevent T2DM**

4.1.1. For primary prevention of T2DM, the Task Force recommends that patients found to be at higher metabolic risk on the basis of multiple metabolic syndrome components be started on a clinical program of weight reduction (or weight maintenance if not overweight or obese) through an appropriate balance of physical activity, caloric intake, and formal behavior modification programs to achieve a lowering of body weight/waist circumference below the targets indicated (see recommendation 1.3. for waist circumference and 4.1.2. for weight) (1 | ++00).

Although it is important to aim for these targets, any lowering of body weight/waist circumference is beneficial, and the Task Force recommends use of lifestyle modification programs for this purpose (1 | ++00).

4.1.2. In individuals at metabolic risk who have abdominal obesity, the Task Force suggests that body weight be reduced by 5–10% during the first year of therapy (2 | +000). Efforts to continue weight loss or maintain the weight loss over the long term should be encouraged.

4.1.3. The Task Force recommends that patients at metabolic risk undergo a program of regular moderate-intensity physical activity (1 | ++00). This activity would be for at least 30 minutes, but preferably 45–60 minutes, at least 5 days/week. It could include brisk walking or more strenuous activity. It can be supplemented by an increase in physical exercise as part of daily lifestyle activities.

4.1.4. The Task Force recommends that all individuals at metabolic risk follow a diet that is low in total and saturated fat, is low in *trans* fatty acids, and includes adequate fiber (1 | ++00). The Task Forces suggest that saturated fat be less than 7% of total calories and dietary cholesterol less than 200 mg/dL (2 | +000). The Task Force recommends that *trans* fat in the diet should be avoided as much as possible (1 | +000). There is much controversy regarding the proportion of carbohydrates in the diet. The Task Forces were unable to reach consensus on the optimal ratio of carbohydrates to fats in the diet. The Task Force recommends that individuals at metabolic risk increase the proportion of fiber, unprocessed grains, and unsaturated fat in their diet. Avoiding foods with high glycemic index may help lower metabolic risk.

4.2. The Task Force recommends that priority be given to reducing risk for diabetes with lifestyle therapies rather than drug therapies (1 | +++0).

Definitions:

Strength of Recommendations

1 - Indicates a strong recommendation and is associated with the phrase "The Task Force recommends."

2 - Denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

Quality of the Evidence

+000 Denotes very low quality evidence

++00 Denotes low quality evidence

+++0 Denotes moderate quality evidence

++++ Denotes high quality evidence

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prevention of cardiovascular disease (CVD) and type 2 diabetes (T2DM) in patients at metabolic risk

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

CONTRAINDICATIONS

Aspirin may be contraindicated in some patients.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Clinical Practice Guidelines are developed to be of assistance to endocrinologists by providing guidance and recommendations for particular areas of practice. The Guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The Guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The Guidelines are not intended to dictate the treatment of a particular patient. Treatment decisions must be made based on the independent judgment of health care providers and each patient's individual circumstances.
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IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Rosenzweig JL, Ferrannini E, Grundy SM, Haffner SM, Heine RJ, Horton ES, Kawamori R, Endocrine Society. Primary prevention of cardiovascular disease and type 2 diabetes in patients at metabolic risk: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2008 Oct;93(10):3671-89. [144 references]
[PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Oct

GUIDELINE DEVELOPER(S)

The Endocrine Society - Disease Specific Society

SOURCE(S) OF FUNDING

The Endocrine Society

GUIDELINE COMMITTEE

Cardiovascular Disease and Type 2 Diabetes in Patients at Metabolic Risk Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: James L. Rosenzweig; Ele Ferrannini; Scott M. Grundy; Steven M. Haffner; Robert J. Heine; Edward S. Horton; Ryuzo Kawamori

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

James L. Rosenzweig, M.D. (*Chair*)—Significant Financial Interests: none declared; Governance: National Diabetes Quality Improvement Alliance; Consultation or Advisement: AMA Physician Consortium for Performance Improvement Advisory Committee, Alere Medical Scientific Advisory Board, Blue Cross-Blue Shield of Massachusetts Advisory Board, National Quality Forum Technical Advisory Panel, Disease Management Association of America Advisory Board; Grant or Other Research Support: Ruby Linn Foundation; Honoraria: Alere Medical, Merck, Healthways; Philips Medical, Sanofi-Aventis; Speakers Bureau: Bristol-Myers Squibb; Merck, Sanofi-Aventis

Ele Ferrannini, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: none declared; Grant or Other Research Support: none declared; Honoraria: none declared; Speakers Bureau: none declared

Scott Grundy, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Pfizer, Abbott, Astra Zeneca, Sanofi Aventis, Merck, Grant or Other Research Support: Merck, Abbott, Kos, GlaxoSmith Kline, Donald W. Reynolds Fund, Veterans Affairs, National Institutes of Health; Honoraria: Merck, Pfizer, Sankyo, Merck/Schering-Plough, Kos, Abbott, Bristol-Myers Squibb, AstraZeneca; Speakers Bureau: none declared

Steven M. Haffner, M.D.— Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Pfizer, Merck & Company, Inc.; Grant or Other Research Support: National Institutes of Health, GlaxoSmithKline, Novartis, Pfizer, Astra-Zeneca; Honoraria: none declared; Speakers Bureau: Sanofi-Aventis, Novartis, GlaxoSmithKline, Merck & Company, Inc., Pfizer, Eli Lilly, AstraZeneca

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Edward S. Horton, M.D.— Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Novartis, Merck, Takeda, Novo Nordisk, Sankyo, Pfizer; Grant or Other Research Support: none declared; Honoraria: Advisory Boards, Data Safety Monitoring Boards, Novartis, Merck, Takeda, Novo Nordisk, Sankyo, Pfizer

Ryuzo Kawamori, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Takeda, Astra Zeneca; Grant or Other Research Support: none declared; Honoraria: none declared. Speakers Bureau: Takeda, Novo Nordisk.

**As of January 1, 2008, Robert J. Heine joined Eli Lilly in Indianapolis as the Executive Medical Director of the Diabetes and Endocrine Division, but retained his affiliation with the Vrije Universiteit Medical Center in Amsterdam, The Netherlands.*

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from [The Endocrine Society](#).

Print copies: Available from The Endocrine Society, c/o Bank of America, P.O. Box 630721, Baltimore, MD 21263-0736; Phone: (301) 941.0210; Email: Societyservices@endo-society.org

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following are available:

- Patient guide on metabolic risk; primary prevention of cardiovascular disease and type 2 diabetes. Chevy Chase (MD): The Hormone Foundation; 2008 Oct. 2 p. Electronic copies: Available in Portable Document Format (PDF) from [The Hormone Foundation Web site](#).
- Patient fact sheet: the metabolic syndrome. Chevy Chase (MD): The Hormone Foundation; 2004 Jan. 2 p. Electronic copies: Available in English and Spanish in Portable Document Format (PDF) from [The Hormone Foundation Web site](#).
- Patient fact sheet: type 2 diabetes screening. Chevy Chase (MD): The Hormone Foundation; 2008 Jan. 2 p. Electronic copies: Available in English and Spanish in Portable Document Format (PDF) from [The Hormone Foundation Web site](#).

Print copies: Available from The Endocrine Society, c/o Bank of America, P.O. Box 630721, Baltimore, MD 21263-0736; Phone: (301) 941.0210; Email: Societyservices@endo-society.org

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NGC STATUS

This NGC summary was completed by ECRI Institute on March 5, 2009. The information was verified by the guideline developer on April 7, 2009.

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